



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097038,470	03/11/98	MEHTA	CELG-0085

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HM22/0621

EXAMINER
BENSTON JR, W

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/038,470

Applicant(s)

MEHTA et al

Examiner

BENSTON

Group Art Unit

1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 6-25-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-3 is/are pending in the application.

Of the above claim(s) is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☐ Claim(s) is/are objected to.

☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 547

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

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15.) Receipt of I.D.S. dated 6-25-98 and 9-4-98 are acknowledged.

16.) Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "For Treating Disease" is vague and indefinite as there is no indication what disease(s) are/is being referred to. A correction/disclosure is requested.

17.) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18.) Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashida et al.

Claims read on dosage forms for oral administration of a methylphenidate drug in a sustained release profile.

Hayashida et al., teaches a composition of methylphenidate (col. 6, L. 48), granules/particles (col. 1, L. 63-65), in an immediate (col. 7, L. 41-42) and sustained release (col. 7, L. 34-39).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Hayashida et al., who teaches an immediate/sustained release tablet/granules.


The intended purpose is to provide a method for treating disease by administering an oral dosage form of once-daily administration of methylphenidate.

No claim is allowed.

19.) Any inquiry concerning this communication or earlier communications from the examiner should be directed to William E. Benston, Jr., whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday-Friday from 9:30 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

 W. Benston:jmr

June 11, 1999


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600